REMARKS

The Office Action of July 6, 2004, has been received and reviewed. Claims 1, 10, 33 and 34 are pending and stand rejected. Applicants expressly reserve the right to prosecute the pending claims and any related claims in a subsequent application. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph:

Claim 10 stands rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement for how to make and use the invention commensurate in scope with the claims. Applicants respectfully traverse the rejection.

Specifically, it was thought that undue experimentation would be required for one skilled in the art to practice the claimed invention since the art was deemed unpredictable, the animal model used to demonstrate the invention and the specification was thought to disclose a limited number of working examples.

As described in the as-filed specification, Examples 2, 3 and 4 are working examples of *in vivo* experiments performed on sensitized mice. The disclosed experiments show a clear and distinct effect of the ability of the claimed peptide to inhibit bronchial constriction (as acknowledged by the Office on page 2 of the Office Action). The disclosed examples teach a person of ordinary skill in the art that the claimed composition inhibits binding of free IgLC to mast cells, and with that teaching a person of ordinary skill in the art is enabled to use the claimed composition to treat the appropriate diseases. The Office seems to be asserting that without *in vivo* data for each disease, the claims are not enabled, which is contrary to the law. "What is necessary to satisfy the how-to-use requirement of s 112 is the disclosure of some activity coupled with knowledge as to the use of this activity" *In re Bundy*, 209 USPQ 48 (CCPA 1981) (citing *In re Gardner*, 177 USPQ 396, 398). Applicants have disclosed activity that, coupled with the knowledge of how to use the activity, enables a person of ordinary skill in the art to make and use the claimed invention without undue experimentation. Reconsideration and withdrawal of the enablement rejections of claims 1-5, 10-13, 16-25 and 31-32 are thus

requested.

Rejections under 35 U.S.C. § 102(b):

Claims 1, 10 and 33 stand rejected as allegedly being anticipated by Huang *et al.*

Applicants respectfully traverse the rejection for the same reasons restated by the Office (*see*, page 6 of the Office Action), but which have not been addressed in the reiterated rejection. First, Huang *et al.* does not disclose a pharmaceutical composition consisting of a peptide of sequence AHWSGHCCL and a pharmaceutically acceptable carrier or diluent. As discussed at the interview, using closed "consisting of" language excludes non-pharmaceutically acceptable carriers and excipients. At most, Huang *et al.* discloses the peptide of SEQ ID NO:1 together with immunoglobulin light chain (LC). LC is not the peptide of SEQ ID NO:1, nor is it a pharmaceutically acceptable carrier or excipient. The reference thus fails to disclose a pharmaceutical composition consisting of SEQ ID NO:1 and a pharmaceutical carrier or excipient and the anticipation rejection clearly fails.

The applicants also note that the Office states in the rejection under 35 U.S.C. § 103 that "[t]he claimed invention differs from the teachings of the reference [Huang *et al.*] only in that a pharmaceutical composition consisting of the peptide consisting of an amino acid sequence of SEQ ID NO:1 and a pharmaceutically acceptable carrier or excipient" (page 8 of the Office Action). Therefore, the Office even acknowledges that Huang *et al.* does not anticipate the claims.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejections under 35 U.S.C. § 103:

Claims 1, 10, 33 and 34 stand rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Huang *et al.* in view of Gennaro *et al.* in Remington's Pharmaceutical Sciences. The Office asserts that because Huang *et al.* teach that the peptide is useful for inhibiting binding of the IgLC to THP a person of ordinary skill in the art would be motivated to make a pharmaceutical composition from the peptide. Applicants respectfully disagree.

Huang *et al.* provides no motivation to use the peptide as a pharmaceutical composition. In particular, Huang *et al.* state that the light chain binding site on THP will help produce strategies that inhibit interaction of LCs with THP ...." (Huang *et al.* at page 736, first column; emphasis added). Thus, Huang *et al.* does not provide motivation to a person of ordinary skill in the art to use a peptide as a pharmaceutical composition, only at most as a further research tool.

In the absence of a teaching by Huang *et al.* that the peptide would be a useful pharmaceutical, motivation to combine the references can only be provided by using impermissible hindsight, which is only provided by the present application. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

If questions remain after consideration of the remarks herein, the Office is kindly invited to contact the applicants' representative at the number or address provided herein.

Respectfully submitted,

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